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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,413	12/17/2003	Ralph R. Binetti	SC66U-US	8915

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EXAMINER	
BOWMAN, AMY HUDSON	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/738,413	BINETTI ET AL.	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/10/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of treating hyperpigmentation or other unwanted pigmentation or skin condition, comprising topically administering a composition comprising one or more siRNA oligomers specific for tyrosinase mRNA in an effective amount to prevent, ameliorate, reduce, and/or eliminate the unwanted skin condition, classified in class 514, subclass 44. **Election of this group requires further election of a single sequence as explained below.**

II. Claims 31-39, drawn to a method of treating, preventing, reducing, ameliorating, and/or eliminating hyperpigmentation or other unwanted pigmentation, comprising providing a composition comprising an siRNA oligomer specific for tyrosinase to an individual in an effective amount to block or reduce tyrosinase enzyme production in skin or hair, wherein the tyrosinase reduction concomitantly inhibits or reduces the synthesis of melanin, classified in class 514, subclass 44. **Election of this group requires further election of a single sequence as explained below.**

III. Claims 40 and 41, drawn to a cosmetic composition comprising one or more siRNA oligomers in an amount effective to prevent, ameliorate, reduce and/or eliminate skin hyperpigmentation or other unwanted skin condition and a cosmetically acceptable vehicle, classified in class 536, subclass 24.5. **Election of this group requires further election of a single sequence as explained below.**

The inventions are distinct, each from the other because of the following reasons:

The invention of group I is unrelated to the invention of group II. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I and II have not been disclosed as capable of use together and have different functions. The invention of group I and the invention of group II are drawn to separate and distinct methods, each having separate method steps. The invention of group I involves topically administering a composition comprising one or more siRNA oligomers specific for tyrosinase mRNA in an effective amount to prevent, ameliorate, reduce, and/or eliminate the unwanted skin condition; whereas the invention of group II involves providing a composition comprising an siRNA oligomer specific for tyrosinase to an individual in an effective amount to block or reduce tyrosinase enzyme production in skin or hair, wherein the tyrosinase reduction concomitantly inhibits or reduces the synthesis

of melanin. The invention of group I does not involve consideration of effective amounts to block or reduce tyrosinase enzyme production in skin or hair, and further does not involve consideration of tyrosinase reduction concomitantly inhibiting or reducing the synthesis of melanin. To search for one of the methods would not necessarily return art for the other method. Therefore, to search and examine more than one of the instantly claimed inventions presents a burden.

The inventions of groups I and II are each unrelated to the invention of group III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of groups I and II have not been disclosed as capable of use together and have different functions than the invention of group III. The inventions of groups I and II are drawn to methods involving compositions comprising an siRNA oligomer specific for tyrosinase. The invention of group III is drawn to a cosmetic preparation comprising any siRNA oligomer and a cosmetically acceptable vehicle. The methods of groups I and II have not been disclosed as capable of use with the cosmetic preparation of group III and the cosmetic preparation of group III can comprise siRNA oligomers that are not specific for tyrosinase. To search for one of the methods would not necessarily return art for the cosmetic preparation of group III. Therefore, to search and examine more than one of the instantly claimed inventions presents a burden.

Claims 4, 32 and 41 are subject to restriction since they are not considered to be a proper genus/Markush. See MPEP 803.02-PRACTICE RE MARKUSH-TYPE CLAIMS- If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush grouping the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 7169, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 4, 32 and 41 recite SEQ ID NOS: 1-6. The Markush/genus of sequences in claims 4, 32 and 41 are not considered to constitute proper genus, as each sequence is structurally unique. Although SEQ ID NOS: 1-6 each comprise nucleotides, it is the sequence of such nucleotides which provides for their activity. Because the sequences, and thus the structures that provide for function differ, and because no common structure is found from one sequence to the next, the restriction is therefore proper. Furthermore, a search of more than

one of the sequences claimed in claims 4, 32 and 41 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one of the claimed sequences. Accordingly, applicants are required to elect one nucleotide sequence from claims 4, 32 and 41 for examination.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is 571-272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of

document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Amy H. Bowman
Examiner
Art Unit 1635

JAMES SCHULTZ
PATENT EXAMINER